K022763

OCT 0 9 2002

510(k) Summary of Safety & Effectiveness

Submitter	Vanguard Medical Concepts, Inc. 5307 Great Oak Drive Lakeland, FL 33815
Contact	Mike Sammon, Ph.D. Director, Research and Development (863) 904-1628 (801) 327-3339 (facsimile) msammon@safe-reuse.com
Date	August 20, 2002
Device	• Trade Name: Vanguard Reprocessed Trocar • Common Name: Surgical Trocars • Classification: 21 CFR 876.1500 – Class II – Laparoscope, General and Plastic Surgery • Product Code GCJ
Indications for Use	Reprocessed trocars are intended to provide a pathway for entry of instruments during minimally invasive surgery, with particular applications in abdominal, gynecological, urological and thoracic procedures.
Contra-indications	Reprocessed trocars should not be used in patients for whom an endoscopic procedure is contraindicated.

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510(k) Summary of Safety & Effectiveness, Continued

Predicate Devices

Trocars legally marketed by the following original equipment manufacturers:

Manufacturer	Trade Name
United States Surgical	AutoSuture™ VISIPORT™
United States Surgical	AutoSuture™ VERSAPORT™
United States Surgical	AutoSuture™ BLUNTPORT™
Apple Medical Corp.	Trocars
Arthrex Arthroscopy Instruments, Inc.	Trocars
Core Dynamics, Inc.	Trocars
Dyonics, Inc.	Trocars
Linvatec Corp.	Trocars

Predicate Devices

Trocars legally marketed by the following 3rd party reprocessors:

Reprocessor	Trade Name
Medical Instruments Technology	Dilating Tip Trocar
Sterilmed, Inc.	Reprocessed Endoscopic Trocar
Adven Medical Corp.	Reprocessed Disposable Trocar
Surgical Instruments	Reprocessed Trocars and Cannulas

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510(k) Summary of Safety & Effectiveness, Continued

Device Description

A trocar is a surgical device consisting of a cannula and an obturator:

Trocar Cannulae are available with smooth or threaded sleeves with 4.5-12mm inner diameters and 5-15cm lengths. Cannulae are equipped with pressure seals for maintenance of pneumoperitoneum during insertion and withdrawal of instruments. Some models are equipped with a side-port for insufflation and desufflation of the operative cavity. Some models are provided with stability anchors inserted over the cannula sleeves to help seal the incision site and maintain cavity pressure.

Trocar Obturators are available in bladed and non-bladed configurations sized 4.5-12 mm. To reduce the risk for vascular or visceral injury, some bladed obturator models are equipped with a safety shield designed to expose the blade during insertion but to retract over the tip once the operative cavity has been penetrated. Non-bladed optical obturators are equipped with a clear tip and an 11-12mm videolaparoscopy channel to allow trocar insertion under direct visual guidance and minimize the risk for internal injury.

Vanguard receives previously used trocars from healthcare facilities; cleans, inspects, tests, applies a unique serial number, repackages, sterilizes by ethylene oxide; and returns them to the healthcare facility for reuse.

Technological Characteristics

The Vanguard reprocessed trocars are essentially identical to the currently marketed OEM devices. No changes are made to the currently marketed device specifications and they possess the same technological characteristics. Materials and performance testing demonstrate that the devices are equivalent and continue to be safe and effective for their intended use.

Test Data

Cleaning, sterilization, and packaging validations; and performance and materials testing all demonstrate that the reprocessed devices perform as intended and are safe and effective.

Conclusion

Based on the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that the Vanguard Reprocessed Trocars are substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 9 2002

Vanguard Medical Concepts
Mike Sammon, Ph.D
Director, Research and Development
5307 Great Oak Drive
Lakeland, Florida 33815

Re: K022763
Trade/Device Name: Vanguard Reprocessed Trocars
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 20, 2002
Received: August 21, 2002

Dear Dr. Sammon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K022763

Device Name: Vanguard Reprocessed Trocars

Indications for Use:

Reprocessed trocars are intended to provide a pathway for entry of instruments during minimally invasive surgery, with particular applications in abdominal, gynecological, urological, and thoracic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological ...

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